



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

October 30, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Spencer J. Harrill
Technical Director
Breast Center Detection Center #3
10512 Park Road
Charlotte, NC 28210

WARNING LETTER

Dear Mr. Harrill:

Your facility was inspected on July 15, 1997 by a representative from the State of North Carolina Department of Environmental Health and Natural Resources, Division of Radiation Protection, under contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

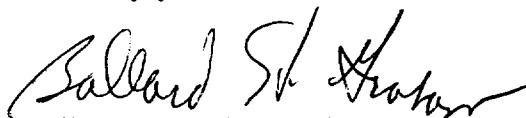
The number of masses scored in the phantom image was 1.5 and did not meet the required number. The minimum number required for masses is 3: TRANSWORLD X-RAY CORP. MAM-CP; MAMMO.

On August 14, 1997 you responded by letter to the noncompliances found during the inspection. We determined that your response appears to be adequate. The corrective action you have implemented will be evaluated during the next inspection. We appreciate your swift action in making these corrections to provide your patients with quality mammograms.

If you had not corrected these violations in a prompt manner, it may have resulted in a regulatory action being initiated by the Food and Drug Administration without further notice. A facility may be subject to civil penalties up to \$10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Standards. A facility may also have its certificate suspended or revoked for failure to comply with the Standards. Continuation or any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in injunction.

If you have any questions regarding this letter please call John J. McCall, Compliance Officer at (404) 347-3162.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with the first name "Ballard" being the most prominent.

Ballard H. Graham, Director
Atlanta District Office

cc: HFI-35
JJM
HFA-224
HFC-210
HFZ-300
HFC-240
HFZ-306
HFZ-322
REK
TURNER
CLT-RP
FILE
LEGAL JKT.
HFA-244
HFC-230
HFZ-240
STATE AGENCY
HFZ-242
T. TROUT
C. FOULKS
S. Harrell